

Message Text

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PAGE 01 STATE 137414
ORIGIN HEW-06

INFO OCT-01 ARA-14 ISO-00 OES-07 SIG-03 EB-08 COME-00
MED-03 /042 R

DRAFTED BY DHEW/FDA: JRWEINROTH, MD:VO
APPROVED BY OES/ENP/EN: WJWALSJ, III
DHEW/PHS/OASH/OIH: MKEFAUVER
ARA/ECA:JBUMPUS(INFO)
ARA/AND/C:DCOX(INFO)
ARA/CAR:GDESANTILLANA(INFO)
ARA/AND/E:JALLITTO(INFO)
ARA/CEN:EHICKS(INFO)

-----025582 311850Z /46

P 311828Z MAY 78
FM SECSTATE WASHDC
TO AMEMBASSY BUENOS AIRES PRIORITY
AMEMBASSY BOGOTA PRIORITY
AMEMBASSY SANTO DOMINGO PRIORITY
AMEMBASSY QUITO PRIORITY
AMEMBASSY SAN SALVADOR PRIORITY
AMEMBASSY PORT AU PRINCE PRIORI

UNCLAS STATE 137414

E.O. 11652: N/A

TAGS:OGEN, ETRD, EIND, TBIO, XX

SUBJECT: FDA ADVISORY - MECHANICAL HAZARD IN ANESTHESIA
VENTILATOR (RECALL T-087-8)

1. FDA ADVISES OF THE FOLLOWING:
A. PRODUCT INVOLVED - OHIO FLUIDIC ANETHESIA VENTILATOR
MODEL NO. 309-0612-800. THE DEVICE IS USED TO PROVIDE
ASSISTED OR CONTROLLED MECHANICAL VENTILATION TO PATIENTS
UNDER ANESTHESIA.
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B. PRODUCT IDENTIFICATION - ALL DEVICES ARE UNDER OHIO
MEDICAL PRODUCTS LABEL. THE DEVICES EACH BEAR A NINE
DIGIT SERIAL NUMBER BEGINNING WITH AAEA, AAEB, AAEC, AND
AAED. THE UNITS WERE MANUFACTURED FROM 1973 THROUGH 1976.
PRODUCTION SINCE DECEMBER 1, 1976 WAS CORRECTED BY A
DESIGN CHANGE IN WHICH THE BELLOW STOPS ARE FURTHER
TOWARD THE CENTER OF THE BELLOWS SO THAT THE STOPS NO

LONGER COME IN CONTACT WITH THE BELLOWS.

C. MANUFACTURER/RECALLING FIRM - OHIO MEDICAL PRODUCTS,
3030 AIRCO DRIVE, MADISON, WISCONSIN 53707

2. REASON FOR RECALL - THE BELLOWS COMPONENT OF THE
DEVICE MAY BECOME WORN PREMATURELY AND DEVELOP SMALL
HOLES DUE TO CONSTANT FRICTION AND RUBBING AGAINST THE
BELLOWS STOP POSTS DURING OPERATION. THIS CONDITION
PRESENTS THE POTENTIALLY SERIOUS HAZARD OF INCREASED
VOLUME OF AIR/GAS MIXTURES BEING DELIVERED TO A PATIENT
REQUIRING CONTROLLED RESPIRATION, AND DEPENDENT ON THE
DEVICE FOR INSPIRATION OF PRESET CONTROLLED VOLUME OF AIR
OR GAS MIXTURE. ONLY ONE COMPLAINT WAS ON FILE AT THE
FIRM INVOLVING THIS DEVICE. ON 6/6/77 AN OHIO MEDICAL
PRODUCTS (OMP) SERVICEMAN IN PORTLAND, OREGON REPORTED
HOLES IN THE BELLOWS ON "OLDER UNITS". THIS COMPLAINT
LED TO DISCOVERY OF THE PROBLEM FOR WHICH THE DESIGN
CHANGE WAS MADE. NO INJURIES HAVE BEEN REPORTED.

3. POSTS ARE REQUESTED TO DETERMINE IF CONSIGNEES ARE
AWARE OF NECESSITY FOR FIELD MODIFICATION OF AFFECTED
DEVICES. THE FIRM HAS DEVELOPED A FIELD MODIFICATION KIT
FOR RETROFIT BY DEALERS WHO HAVE RECEIVED DEFECTIVE UNITS.
THE FIRM EXPECTS TO COMPLETE FIELD MODIFICATION IN 4 MONTHS.
ANY INQUIRIES REGARDING THIS ADVISORY SHOULD BE REFERRED
TO FIRM, ATTENTION MR. MICHAEL F. RICCIO, MANAGER PRODUCT
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SAFETY, 608-221-1551.

4. FOREIGN CONSIGNEES AS FOLLOWS:

LUT" FERRANDO Y CIA. S.A. CELIN PAULEMON
FLORIDA 240 P.O. BOX 244
1005 BUENOS AIRES, ARGENTINA PORT-AU-PRINCE, HAITI

TECNICA ELECTRO MEDICA IRAN BEHDASHT CO. LTD.
APARTADO AERO 3752 P.O. BOX 12-1144
BOGOTA, COLOMBIA 118/122 WEST TAKHTE
-- JAMSHID AVE.
CALMEST C POR A TEHRAN, IRAN
P.O. BOX 1693 ZONA 8
SANTO DOMINGO, DOMINICAN REP AMCO INCORP.
-- 8-7, 4-CHOME, IIDABASHI,
ECUAMEDICA CHIYODA-KU
AV. STA. PRISCA Y PASAJE FARGET, TOKYO, JAPAN
CASILLA 1156
QUITO ECUADOR NZIG MEDISHIELD
146-148 ADELAIDE RD.
MARCELO J. WOLFF Y CIA WELLINGTON, PRIVATE BAG

CALLE ARCE 1219 WELLINGTON SOUTH
SAN SALVADOR, EL SALVADOR NEW ZEALAND

LA CASA DEL MEDICO MUNDINTER SARL
APARTADO POSTAL 1689 AV ANT AUG AGUIAR 138
PANAMA CITY, PANAMA P.O. BOX 2761

-- LISBON, PORTUGAL

CALMAQUIP ING.

LOS FICOS 359 JARDINE PARRISH S PTE LTD.
SAN ISIDRO, LIMA, PERU 287/297D SELEGIE COMPLEX

-- SELEGIE RD.

INDURA S.A. SINGAPORE 7, MALAYSIA

CASILLA 16439, CORREO 9

SANTIAGO, CHILE FREDERICK C. MARCUS, CO.

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-- P.O. BOX 3039

SCHRAMM TRADING APS. CAPE TOWN 800
ISLEVDALVEJ 211, DK 2610 RODOVRE SOUTH AFRICA

COPENHAGEN, DENMARK

-- LAUBSCHER AND CO.

DEBAKEY BROS. AND CO. RHEINSRUNG 5 POSTFACH
P.O. BOX 382 ROXY, HELIOPOLISH CH-4001 BASEL, SWITZERLAND

CAIRO, EGYPT

-- ERMAL MEDICAL INSTRUMENTS

E. GAVALA LARIGOS AND CO. SIHHIYE, MITHAT PASA CAD.

P.O. BOX 350, 18020 ANAST. TSOCHA NO. 10/9

ATHENS 602 GREECE ANKARA, TURKEY

INSTRUMENTS AND MACHINES, INC. MEDALFA C.A.

4, ARUMUGA NAICKEN ST. MOUNT RD. APARTADO POSTAL 75.575

MADRAS 600 002 INDIA CARACAS 107, VENEZUELA

CORALMA S.A.S. GUIDO RAYOS X

P.O. BOX 773, VIA CORSICA 2-1 APARTADO DE CORREOS 4110

16128 GENOA, ITALY MADRID 4, SPAIN

SHIN HAN SCIENTIFIC CO. LTD. SHENG TUND DEVELOPMENT CO.

CPO BOX 1250 NO. 1-1 NANKING WEST RD

SEOUL, KOREA P.O. BOX 451

-- TAIPEI, TAIWAN

REPRESENTACIONES MEDICOTECHNICAS S.A.

MAZATLAN 83, DEPT 101

MEXICO DF 11, MEXICO COLIMODIO S.A.

-- APARTADO 1053

ROBERTO TERAN G. CARACAS, VENEZUELA

APARTADO 689

MANAGUA, NICARAGUA HOYER BREMEN

-- 2800 BREMEM 1

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AMERICAN HOSPITAL SUPPLY CORP. PARKALLEE 44, WEST GERMANY
P.O. BOX 4436
LIMA, PERU

WHITTAKER CORP.
BIOMEDICAL DEPT.
P.O. BOX 3838
JEDDAH, SAUDI ARABIA CHRISTOPHER

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NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01 jan 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: MEDICAL EQUIPMENT, RECALLS
Control Number: n/a
Copy: SINGLE
Draft Date: 31 may 1978
Decaption Date: 01 jan 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 jan 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1978STATE137414
Document Source: CORE
Document Unique ID: 00
Drafter: JRWEINROTH, MD:VO
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Expiration:
Film Number: D780227-1059
Format: TEL
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1978/newtext/t1978052/aaaaabiv.tel
Line Count: 183
Litigation Code IDs:
Litigation Codes:
Litigation History:
Locator: TEXT ON-LINE, ON MICROFILM
Message ID: efbfba96-c288-dd11-92da-001cc4696bcc
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 4
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Retention: 0
Review Action: RELEASED, APPROVED
Review Content Flags:
Review Date: 29 mar 2005
Review Event:
Review Exemptions: n/a
Review Media Identifier:
Review Release Date: N/A
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 2571678
Secure: OPEN
Status: NATIVE
Subject: FDA ADVISORY - MECHANICAL HAZARD IN ANESTHESIA VENTILATOR (RECALL T-087-8)
TAGS: OGEN, ETRD, EIND, TBIO, XX
To: BUENOS AIRES BOGOTA MULTIPLE
Type: TE
vdkgvwkey: odbc://SAS/SAS.dbo.SAS_Docs/efbfba96-c288-dd11-92da-001cc4696bcc
Review Markings:
Sheryl P. Walter
Declassified/Released
US Department of State
EO Systematic Review
20 Mar 2014
Markings: Sheryl P. Walter Declassified/Released US Department of State EO Systematic Review 20 Mar 2014